DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-25

August 11, 2006

Janusz M. Szyszko
President, Chief Executive Officer
Pointe Scientific Inc
5449 Research Drive
Canton, MI 48188

Dear Mr. Szyszko:

The Food & Drug Administration (FDA) conducted an inspection of your facility located in Canton, MI on May 4-June 16, 2006. Our investigation determined that your firm is an in-vitro diagnostic manufacturer of Hemoglobin A1c; two separate products of Liquid Glucose Hexokinase; Liquid Alkaline Phosphatase; Liquid Auto Density Lipoprotein (Auto HDL) Cholesterol; and others used for chemical analyzers. These products are defined as devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h).

This inspection revealed that these devices are adulterated under section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations from CGMP requirements include, but are not limited to, the following:

1. Your firm failed to establish procedures to control the design of devices to ensure specified requirements are met, as required by 21 CFR 820.30(a). For example, written procedures for controlling the design of the Hemoglobin A1c Reagent and formulation changes to the Liquid Glucose Hexokinase Reagents were not adequately established during the implementation of these design projects. In addition, design history files do not demonstrate that these devices were developed in accordance with the design control requirements as required by 21 CFR 820.30(j).

2. Your firm failed to ensure complaints involving possible failures are adequately reviewed and evaluated to determine if investigations are necessary as required by 21 CFR 820.198(c). For example, your firm received approximately 7 complaints involving the Liquid Glucose Hexokinase (Hitachi); 20 complaints involving the Liquid Alkaline Phosphatase; 4 complaints involving the Liquid Glucose Hexokinase; and 5 complaints involving the Ammonia and Alcohol Control and Alcohol Standard and no investigations were conducted.

3. Your firm failed to establish procedures for the evaluation of suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example, there is no documentation to demonstrate that your firm has evaluated the importer or is aware of the manufacturer from Asia supplying the reagents used to produce the Hemoglobin A1c Reagent. In addition, there are no clear agreements from the suppliers to notify you of changes, as required by 21 CFR 820.50(b). For example, supplier formulation changes to the Liquid Auto HDL Cholesterol Reagents resulted in the receipt of 15 complaints of product failures by your firm.

4. Your firm failed to establish effective and complete procedures for implementing corrective and preventative action operations, as required by 21 CFR 820.100. In addition, certain indicators of non-conformances are not investigated to determine root causes. For example, there were at least 10 non-conformances varying from stability failures, fungus, mold growth, and low recoveries and no investigations were conducted to determine root causes.

5. Your firm failed to establish effective and complete procedures for addressing non-conforming product, as required by 21 CFR 820.90(a).

6. Your firm failed to maintain complete Device Master Records (DMR) that include all the elements required by 21 CFR 820.181. For example, DMRs are incomplete for the Hemoglobin A1c; Liquid Glucose Hexokinase Reagents; Liquid Alkaline Phosphatase; and Liquid Auto HDL Cholesterol devices.

7. Your firm failed to validate your manufacturing processes as required by 21 CFR 820.75(a). For example, your firm has not validated the following manufacturing processes: deionized water system, mixing, filtration, grinding, cleaning, and freezing used to manufacture the Liquid Alkaline Phosphatase and Liquid Glucose Hexokinase Reagents.

8. Your firm failed to establish procedures and monitor production process parameters, as required in 21 CFR 820.70(a). For example, your procedures for the deionized water system has not been implemented or adequately monitored.

9. Your firm failed to validate computer software used to control automated production and quality system operations, as required by 21 CFR 820.70(i). For example, your firm has not validated the software used to produce labels and manage your complaints.

10. Your firm failed to establish effective procedures for or to conduct quality audits, as required by 21 CFR 820.22.

11. Your firm failed to follow procedures for controlling the storage of product in order to prevent mix-ups, damages, or other adverse effects as required by 21 CFR 820.150(a). For example, your temperature control policy requires daily temperature monitoring and immediate quarantine of products exposed to potentially deleterious conditions. However, review of your 2005 temperature logs revealed these procedures were not always implemented.

12. Your firm failed to establish and provide training to ensure employees adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, you have not established procedures or assured employees responsible for design, development, quality assurance, regulatory affairs, and production have received training related to the Quality System regulations.

13. Your firm has failed to establish and maintain adequate written medical device reporting (MDR) procedures, as required by Section 519 of the Act (21 U.S.C. 360i) and the MDR Regulations, 21 CFR Part 803.

14. Management with executive responsibility has failed to ensure that an adequate quality system, as defined in 21 CFR 820.3(v), has been fully implemented and maintained at all levels of your organization, as required by 21 CFR 820.20, as is evident by the observations listed above.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure adherence to each applicable requirement of the Act and regulations. You must also promptly initiate permanent corrective and preventative action of your quality system.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no request for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge your July 2006 letter responding to the FORM FDA-483 issued at the conclusion of the inspection. The response letter describes commitments toward corrective action, and implementing appropriate procedures, policies, and documentation to improve effectiveness of the quality system above. However, the response does not appear to definitely commit to performing all the design control and design history file requirements per 21 CFR 820.30; and controlling production processes per 21 CFR 820.70. Specifically, the response fails to outline specific steps your firm will take to correct these violations and prevent reoccurrences. We also believe your firm needs to fully evaluate your record keeping system, especially Design History Files, Device Master Records, and Production Monitoring Records to ensure other deviations will not occur. In addition, the response indicates a QSR consultant will be obtained. We encourage you to ensure consultants are evaluated per 21 CFR 820.50.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter, as to the specific steps you have taken to correct these violations. You should also include a detailed explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time frame which the corrections will be implemented. Your written reply should be directed to Paige E. Wilson, Compliance Officer at the above address.

Sincerely,

Joann M. Givens
District Director
Detroit District Office